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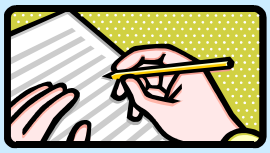

Notes from the Editor

The ADS Newsletter was developed as part of an EPO effort to enhance communication and information sharing within EPO and across CDC. Over the past 2 years and after nine issues, many topics relating to science, ethics, and policy were discussed. We hope that you have found the past issues helpful in providing guidance and resources relating to these topics. This special edition revisits some of these topics with a focus on human subjects review (HSR), institutional review board (IRB), and consent procedures and requirements.

If you have any suggestions for future topics or would like to contribute articles to future issues, please contact Aun Lor at 404-639-1488 or alor@cdc.gov.

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CDC Human Subjects Activity/IRB Requirements for Translation of Consent Forms and Documents Used for Human Subjects Research

Although federal regulations, including the *Code of Federal Regulation, title 45, Part 46: Protection of Human Subjects* (aka, the Common Rule), do not specifically address translation, the policy of the CDC Institutional Review Boards (IRBs) is to ensure that adequate provisions have been made by investigators to translate consent documents and other documents to be used during interactions with non-English speaking participants involved in our research activities so that participants will have the necessary understanding of the research project and the procedures involved before giving their consent, either verbally or in writing.

Investigators may either 1) have the translation completed by a certified translator and provide the name and organizational affiliation of the person to the IRB, or 2) have the translation completed "in house," have another individual complete a back-translation (someone not associated with the research project), and then attest to the IRB that the translation is satisfactory.

Research participants who do not speak English should be presented with a consent document written in a language understandable to them. When written documentation is not feasible, oral presentation of informed consent information in conjunction with a short written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally can be used. A witness to the oral presentation is required, and the participant must be given copies of the short written consent document and the summary. When this procedure is used with participants who do not speak English, the oral presentation and the short written consent document

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Ethical Dilemma in Public Health

Scenario – A CDC fellow assigned to a local health department took part in the design and implementation of a research study involving human subjects. The fellow initially discussed his involvement with his CDC supervisor regarding obtaining CDC IRB approval but, through a series of mishaps and miscommunications, failed to submit a protocol to CDC IRB. The protocol was submitted to the local IRB, received approval, and implemented with full participation by the fellow.

What are the consequences for not obtaining CDC IRB approval?

The most obvious consequence is that the fellow involvement in the research will be immediately terminated upon CDC discovery. Other consequences include the fellow not being able to participate further in the project and not being able to include his name in any publication resulted from the study. The fellow could be guilty of research misconduct for not following appropriate CDC policy and procedures. CDC policy requires that all CDC investigators follow appropriate CDC procedures, which in this case include obtaining CDC IRB approval and taking the CDC Scientific Ethics training before participating in any research involving human subjects. Although in this case, other factors, (i.e., supervisory and other management issues,) might have contributed to the investigator's failure to obtain CDC IRB approval, it is ultimately the investigator's responsibility to be familiar with and follow appropriate CDC procedures.

HIPAA Update: EPO to Reconstitute the Privacy Rule Workgroup

The Health Information Privacy Office (HIPO), Epidemiology Program Office (EPO), is pleased to announce the reconstitution of the Privacy Rule Workgroup. The workgroup, which originally included approximately 24 members with representation from every CIO at CDC, first met on September 4, 2002. The objectives of the workgroup include assuming leadership for defining the nature of the Privacy Rule as it relates to public health programs, establishing an industry-wide understanding of the impact of the privacy rule on public health programs, and evaluating the impact of the Privacy Rule on public health programs. The workgroup's accomplishments include:

- Providing substantial guidance on the drafting of the "HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services" published in an *MMWR* special supplement in April 2003 - http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm;
- Participating on numerous Privacy Rule forums and Public Health Grand Rounds;
- Developing materials for the CDC Privacy Rule website (http://www.cdc.gov/privacyrule).

HIPO is looking forward to working with both new and old members to continue providing guidance on the Privacy Rule to CDC staff, its partners, and the public health community. The first meeting of the reconstituted workgroup was on April 26, 2004.

For more information about HIPO, the Privacy Rule Workgroup, and other related issues, please contact Beverly Dozier, Privacy Rule Coordinator, at 404-639-3683, Bdozier@cdc.gov or Linda Shelton at 404-639-3683, Lshelton@cdc.gov.

Frequently Asked Questions

1. How do you define "research"?

The Common Rule (45 CFR 46) defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

(For more details see section 2a in the EPO Overview of Scientific Procedures at http://www.cdc.gov/epo/ads/section-iia.htm).

2. How do you define "investigator"?

CDC defines an investigator as CDC staff who work directly or in collaboration with an outside party in the design of a research study, development of methods and procedures for the study, collection of data, analysis of data, or interpretation of data.

(For more details see CDC /ATSDR Procedures for Protection of Human Research Participants: 2003 - http://www.cdc.gov/od/ads/procphrp.pdf).

3. How do you define "consultant"?

A consultant to a research project is someone who gives professional advice to the project investigator(s). CDC staff members migh be designated as a consultant on human subjects research projects if they meet all of the following criteria:

- Consultant cannot interact or intervene with human subjects for research purposes.
- Consultant cannot possess or obtain personally identifiable information.
- Consultant must limit their activities to reviewing and providing advice to the non-CDC investigators regarding scientific activities related to the project (e.g., study design, sampling, recruitment, and questionnaire development);
- The non-CDC investigators must have autonomy in making research decisions
- Consultant may coauthor manuscripts with the non-CDC investigators but generally should not be the first author on any manuscript describing the major and most significant research findings associated with the study.

(CDC/ATSDR Procedures for Protection of Human Research Participants: 2003 for more details - http://www.cdc.gov/od/ads/procphrp.pdf)

4. How do you define "human subject"?

The Common Rule (45 CFR 46.102) defines human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

(For more details see the *Code of Federal Regulation, title 45, Part 46: Protection of Human Subjects* http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm)

5. What does "minimal risk" means?

According to the Common Rule, "minimal risk" means that the **probability** and **magnitude** of harm or discomfort anticipated in the research are not greater in and of

Continued on page 3:FAQs

Scientific Ethics Training

As a reminder, if you are planning to conduct research involving human subjects, you are required to take the CDC Scientific Ethics Training.

Each year, CDC and ATSDR scientists conduct several hundred studies throughout the world that involve people as research subjects. At the backbone of a strong public health science base is the practice of ethically responsible science. However, ethical issues encountered in public health research are different from those encountered in clinical medicine. To help ensure that our public health research is ethically grounded, a computer-based training program entitled *Scientific Ethics* has been developed. All scientific staff and managers will be required to complete the training before they conduct research at CDC or ATSDR. Upon completion of this training, CDC and ATSDR investigators will be better able to address ethical issues they encounter as they conduct research to improve the public's health.

If you have access to the CDC Intranet, the training can be taken online at http://intranet.cdc.gov/od/ads/ethicstrain.htm. A CD-ROM is also available from your EPO supervisor or the EPO ADS. After completing the training and taken the final exam, the investigator should submit their score along with the file "testres.txt" to their supervisor. This file will be automatically generated and store in the hard drive and can be found by searching through the c:drive. The supervisor will submit the ethics score to apply to obtain an ethics number.

Contact your EPO supervisor or Aun Lor (alor@cdc.gov) for more information.

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should be in a language understandable to the participant. The IRB-approved English language informed consent can serve as the summary, and the witness should be fluent in both English and the language of the participant.

A standardized, short, form-written consent document that meets regulatory requirements is available in 19 languages on the CDC intranet and internet web sites (http://intranet.cdc.gov/od/ads/hsrconsent.htm or http://www.cdc.gov/od/ads/hsrconsent.htm). The languages are:

Amharic	Hindi	Punjabi	Tagalog
Arabic	Korean	Russian	Thai
Chinese	Laotian	Serbian	Urdu
English	Polish	Spanish	Vietnamese
French	Portuguese	Swahili	

In addition, when providing documentation of current, local IRB approval from foreign collaborators, please forward a copy of the approval in the local language and a copy of the English translation. This documentation should be included in the continuation request as it is submitted to the Human Subjects Activity.

For more information please contact Pam Galusha, IRB Administrator, at 404-498-3102.

CDC Human Subjects Activity Training Calendar

These trainings are open to any CDC staff interested.

Month	Topic	Date/Time	Place
July '04	FDA Regulations: Ins & Outs of INDs & IDEs	7/12/04 (11a-1p)	ExPk Bg 31, CR 3100
August '04	How to Write a Protocol	8/2/04 (11a-1p)	ExPk Bg 31, CR 3100
September '04	45 CFR 46: The HHS HS Federal Regulations	9/13/04 (11a-1p)	ExPk Bg 31, CR 3100
October '04	Collaborative Research: Assurances, Deferrals, & IIAs	10/4/04 (11a-1p)	ExPk Bg 31, CR 3100
November '04	The CDC IRB Process: What to Expect, Including Form Usage	11/1/04 (11a-1p)	ExPk Bg 31, CR 3100
December '04	How to Write & Respond to an IRB Report	12/6/04 (11a-1p)	ExPk Bg 31, CR 3100
January '05	OMB/IRB/P&CB	1/10/05 (11a-1p)	ExPk Bg 31, CR 3100
February '05	Genomics in HS Research	2/7/05 (11a-1p)	ExPk Bg 31, CR 3100
March '05	Adverse Events, Clinical Trials & GCP Basics	3/7/05 (11a-1p)	ExPk Bg 31, CR 3100
April '05	Specimen Storage	4/4/05 (11a-1p)	ExPk Bg 31, CR 3100
May '05	Date Management	5/2/05 (11a-1p)	ExPk Bg 31, CR 3100
June '05	Informed Consent	TBA (11a-1p)	ExPk Bg 31, CR 3100

EPO ADS Staff Update

Please join us in welcoming **Beverly Dozier, J.D.**, who serves as the new CDC Privacy Rule Coordinator in the Health Information Privacy Office (HIPO), Epidemiology Program Office (EPO).

Beverly was born in Ocala, Florida and attended high school in Miami. She earned her Bachelor of Arts degree in religious studies with honors from Stetson University in DeLand, Florida, and was inducted as a member of Phi Beta Kappa in 1997. She attended the University Of Florida College Of Law and earned her degree as a Juris Doctor in 2000. She attended the University Of Georgia School Of Law as a visiting student for her third year of law school, and was admitted to practice law in Georgia under the third year practice rule.

After law school, Beverly worked in the Public Defender's Office in Athens-Clarke County representing indigent criminal defendants in both the State and the Superior Court for 1 year and never lost a case. In 2000, she was accepted into the Presidential Management Intern Program and interviewed for positions at CDC as policy analyst. She was hired by the National Center on Birth Defects and Developmental Disabilities (NCBDDD) as a Program Analyst in the Office of the Director. While at NCBDDD, she worked on policy, legislation, and budget and gained expertise on the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Family Educational Rights and Privacy Act (FERPA), Office of Management and Budget (OMB) procedures, Freedom of Information Action (FOIA), and other federal regulations that affect CDC. In March of 2003, Beverly was detailed for EPO to the Office for Civil Rights (OCR) in Washington, D.C., to assist in the implementation of HIPAA. After her return to Atlanta, she accepted the position of "Acting" Privacy Rule Coordinator for EPO. On Feb 22, 2004, Beverly accepted the Privacy Rule Coordinator position on a permanent basis.

Beverly can be reached at 404-639-3683 or Bdozier@cdc.gov.

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themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(For more details see the *Code of Federal Regulation, title 45, Part 46: Protection of Human Subjects* http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm)

6. As a CDC assignee to a local health department, do I need CDC IRB approval for a research study involving human subjects if there is already a local IRB approval?

CDC employees cannot conduct or join any human subjects research study without first obtaining IRB approval or deferral from CDC, or if it is an exempt research, getting an exemption approval from the CDC Deputy ADS.

11) In which cases, if ever, will CDC IRB consider reviewing a project/study that has already started?

CDC IRB will consider reviewing an existing study if a CDC investigator is being asked to join the study and has not previously participated in the project.

12) What is the CDC contact information that I can list in the consent document for research participants to contact when they have questions about their rights as research subjects?

You can use the following statement:

"If you have questions about your rights as a subject in this research study, please call 1-800-584-8814, leave a message including your name and phone number, and someone will call you back as soon as possible."

For more information on any of the above questions please follow the links provided under the questions or contact Aun Lor - 404-639-1488 or alor@cdc.gov.

Upcoming Workshops

These workshops are co-sponsored by the Office for Human Research Protections (OHRP), Department of Health and Human Service (DHHS).

- **May 6-7, 2004**

"Quality Improvement for Research Subject Protection"

Philadelphia, Pennsylvania

Information and Registration - http://www.med.upenn.edu/ohrpconf/

- **July 8-10, 2004**

"Human Subjects Protections In Gene Transfer Research"
With a Pre-Conference Workshop
PRIM&R "IRB 101[sm] On the Road" Workshop

Chicago, Ilionois

Information and Registration - http://www.rush.edu/research/pdfs/OHRPF13.pdf

- **August 2-3, 2004**

"Roadmap for Success in International Research: Strategies for Protecting Human Research Subjects Abroad"

Chapel Hill, North Carolina

Information and Registration - https://register.rti.org/internationalIRB/

EPO ADS Newsletter

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